**Deviation and Nonconformance Investigation Report**

**DNRN # \_\_\_\_\_\_\_\_\_**

|  |
| --- |
| **Deviation / Nonconformance details** |
| Discovery Date/Time |  |
| Location (area, room, zone, etc.) |  |
| Observers (Names, positions) |  |
| Related Documents and Records |  |
| Related Equipment and Facilities (IDs) |  |
| Affected products, materials, processes |  |
| Detailed description of the Event: |
| Initial assumed Event type | ☐ Deviation ☐ Nonconformance |
| Initial assumed Category | ☐ Minor ☐ Major ☐ Critical |
| Corrections were taken prior Deviation and Nonconformance Notification submission: |
| Segregation measurements were taken for Nonconforming Products or Materials prior Deviation and Nonconformance Notification submission: |

|  |
| --- |
| **Scope of investigation** |
| Departments/Teams/functions to be involved |  |  |

|  |
| --- |
| **Investigators:** (to be signed off by all involved subject matter experts) |
| Name | Department/Position |
| Name | Department/Position |
| Name | Department/Position |

|  |
| --- |
| **Assessment and reviewing details** |
| Interviewing with Originator, Observers, other personnel |  |
| Documents and records review |  |
| SOPs review |  |
| Equipment, systems, facilities review |  |
| Premises, rooms, areas review |  |
| Personnel review |  |
| Materials review |  |
| Others |  |

|  |
| --- |
| **Review of Deviation / Nonconformance Type and Category**Initial assumed Event Type and Category shall be reviewed justified by investigators according to Quality Risk Management procedure. |
| Reviewed Event type | ☐ Deviation ☐ Nonconformance |
| Reviewed Category | ☐ Minor ☐ Major ☐ Critical |

|  |
| --- |
| **Chronological description investigation progress (dates, actions, observations, results)** |
|  |

| **Risk Assessment Summary** |
| --- |
|  |

|  |
| --- |
| **Root Cause analysis Summary** |
|  |

|  |
| --- |
| **Impact on Product/Process Summary** |
|  |

|  |
| --- |
| **Escalation proposals** |
|  |

|  |
| --- |
| **Additional Corrections were taken after Deviation and Nonconformance Notification submission:** |
|  |

|  |
| --- |
| **Additional segregation measurements were taken for Nonconforming Products or Materials after Deviation and Nonconformance Notification submission:** |
|  |

|  |
| --- |
| **Final disposition decision for Nonconforming Products or Materials:** |
|  |

|  |
| --- |
| **Proposed CAPAs** |
| **Reference CAPA number** | **Description** |
| **Reference CAPA number** | **Description** |

|  |
| --- |
| **Deviation and Nonconformance Investigation Report Conclusion and proposals** |
|  |

|  |
| --- |
| **Deviation and Nonconformance Investigation Report prepared by:** (to be signed off by all involved investigators) |
| Investigator | Name/Date/Signature |
| Investigator | Name/Date/Signature |

|  |
| --- |
| **Deviation and Nonconformance Investigation Report reviewed by:** (to be signed off by Department Heads of involved subject matter experts) |
| Department Head or Team Lead | Name/Date/Signature |
| Department Head or Team Lead | Name/Date/Signature |

|  |
| --- |
| **Deviation and Nonconformance Investigation Report approved by:** |
| Quality Management Director | Name/Date/Signature |